

### REMARKS

Claims 90-96 and 113-131 are pending in the application. In the Office Action mailed November 17, 2008, claims 90-96 and 113-131 are rejected. In the instant Amendment, claim 118 has been amended to correct an editorial error.

No new matter has been added by the amendment. Entry of the foregoing amendment and consideration of the following remarks are respectfully requested.

Claims 90-96 and 113-131 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. patent No. 6,322,819 ("Burnside") in view of U.S. patent No. 4,326,525 ("Swanson"). In the Office Action, the Examiner asserts that a combination of Burnside, which discloses a multiple pulsed dose delivery system containing methylphenidate with a disintegration agent and a hydrogel, and Swanson, which discloses a dosage form containing methylphenidate and tannic acid, renders the dosage form recited in the present claims obvious because Applicants have not shown that the recited amounts of superdisintegrant, hydrogel, and tannic acid provide unexpected result to the claimed formulation.

For reasons discussed in the Amendment filed on September 24, 2008, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness based on Burnside and Swanson. Nonetheless, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 ("the 132 Declaration") by Vered Rosenberger, Ph.D., a named co-inventor of the present application. The 132 Declaration shows that gel formulation should contain superdisintegrant, tannic acid, and hydrogel in relative amounts within the respectively recited ranges to have good expansion and strength suitable for use as a gastric retention vehicle. For example, Table 1 of the 132 Declaration shows that optimal overall expansion and strength was achieved with about 4% to 8% tannic acid for gel formulations having about 30%±2% of superdisintegrant (croscarmellose sodium). Table 2 of the 132 Declaration shows that a gel formulation containing no tannic acid exhibited virtually no expansion, while the amount of tannic acid could be increased to about 10% if the amount of croscarmellose sodium was reduced to about 22%. Furthermore, according to the declarant's experience, the amount of tannic acid can be decreased to about 2%, if the amount of the superdisintegrant is increased to higher than about 32%, and the relative amounts of Klucel and Methocel are adjusted.

The experimental data demonstrate that to achieve expansion and strength suitable for use as a gastric retention vehicle, a gel formulation must contain the appropriate relative amounts of superdisintegrant, tannic acid, and hydrogel. Therefore, simply combining Burnside's teaching of a formulation containing methylphenidate with a disintegration agent and a hydrogel with Swanson's teaching of including tannic acid would not have led a person skilled in the art to a gel formulation suitable for use as a gastric retention vehicle. Neither Burnside nor Swanson teaches or suggests the importance of having the appropriate relative amounts of superdisintegrant, tannic acid, and hydrogel in a gel formulation for achieving suitable expansion and strength. A person skilled in the art, based on the cited references, would not have expected such an effect of the relative amounts of superdisintegrant, tannic acid, and hydrogel on expansion and strength of a gel formulation, much less a formulation having the recited amounts of superdisintegrant, tannic acid, and hydrogel useful for gastric retention. Therefore, Burnside in combination with Swanson would not have rendered the presently claimed invention obvious.

Claims 90, 93, 116 and 117 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Burnside in view of Swanson in further view of U.S. patent no. 5,847,090 ("Baker"). The Examiner indicates that claims 90 and 93 are rejected as being obvious over Burnside in view of Swanson, while Baker is cited for its teaching that methylphenidate can be used to treat hyperactivity. As discussed above, claims 90 and 93 are not obvious over Burnside and Swanson. Since Baker does not teach inclusion of hydrogel, superdisintegrant, and tannic acid in its formulation, Baker does not supply what is missing in Burnside and Swanson with respect to claims 90 and 93. Claims 116 and 117 are method claims dependent on claims 90 and 93, respectively. Since the base claims 90 and 93 are not obvious over Burnside, Swanson and Baker, claims 116 and 117 are also not obvious.

For all of these reasons, Applicants respectfully submit that claims 90-96 and 113-131 are not obvious over Burnside and Swanson, and claims 90, 93 and 116-117 are not obvious over Burnside, Swanson and Baker. The rejections of these claims under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to

telephone the undersigned at the telephone number indicated below to discuss the same. The Commissioner is hereby authorized to charge the fee for a one-month extension of time, and any other fees required for consideration of this paper, to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully Submitted,

KENYON & KENYON

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